REMARKS

I. Amendments

The specification has been amended to include references to SEQ ID NOs in the description of the drawings. As the sequences described in Figures 1A, 3, 5, 10, and 41 are included with the Sequence Listing, a substitute Sequence Listing is not necessary. With respect to the Examiner's assertion that "Figure 2A is referenced as 1A," Applicants direct the Examiner's attention to the formal replacement sheets (and not to the annotated sheet showing changes) filed in Applicant's response on December 10, 2004.

Claims 37, 42, 44, and 49 are pending. Claims 37 and 44 are amended to more clearly recite the intended claimed subject mater. Support for the amendments can be found in the specification as filed at, for example, page 5, line 8, and page 14, line 5.

The amendments include no new matter.

II. The rejection of claims 37, 42, 44, and 49 under 35 U.S.C. § 103(a) may be withdrawn.

Claims 37, 42, 44 and 49 stand rejected under 35 U.S.C. § 103(a) as assertedly unpatentable over Kosik et al. (Proc. Natl. Acad. Sci., USA, 1986, Vol. 83, pp. 4044-8) ("Kosik") in view of Harlow and Lane, 1988 (Antibodies, Laboratory Manual, Cold Spring Laboratory, pp. 77, 96-97) ("Harlow and Lane"). Claims 37, 42, 44 and 49 also stand rejected under 35 U.S.C. § 103(a) as assertedly unpatentable over Vooheis, U.S. Patent No. 5,492,812 ("the '812 patent") in view of Harlow and Lane, 1988 (Antibodies, Laboratory Manual, Cold Spring Laboratory, pp. 77, 96-97). Applicants respectfully traverse.

At page 5 of the Office Action the Examiner asserts that the broadest reasonable interpretation of the claimed invention is that the composition comprises a tau peptide and a carrier. In view of the claim amendments herein, however, the present invention provides immunogenic compositions and methods useful for the production of antibodies that differentiate between tau protein that is phosphorylated at Serine 262 versus tau protein that is not. Specifically, claims 37 and 44 have been amended to recite "...an antibody which distinguishes between phosphorylated and dephosphorylated tau." Neither Kosik nor the '812 patent disclose or suggest specific phosphorylatable residues and/or specific fragments/epitopes of tau. The sections of the '812 patent cited by the Examiner, for example, disclose two large fragments of amino acid residues 1-151 and 154-352. The '812

patent does not disclose or even suggest the specific phosphorylatable fragment/epitope of tau as set forth in the present claims, let alone such a fragment for the purpose of generating an antibody that can distinguish between phosphorylated and dephosphorylated tau. Accordingly, claims 37, 42, 44 and 49 can not be rendered obvious in view of any combination of Kosik, the '812 patent, and Harlow and Lane.

With respect to the Examiner's interpretation of the meaning of the phrase "consisting essentially of," the Examiner asserts that "...the essential structure of a peptide is defined by a specific number and order of amino acid units" and that "...addition of another amino acid molecule to either end of a fragment...would, by definition, primarily and "materially affect the basic and novel characteristic(s) of the claimed invention"." The Applicants do not dispute this point. However, Applicants again point out that MPEP § 2111.03 states, "[t]the transitional phrase 'consisting essentially of' limits the scope of a claim to the specified materials or steps 'and those that do not materially affect the basic and novel characteristic(s)' of the claimed invention. (emphasis in original) Thus, the term "consisting essentially of" in the amended claims relates to a specific and phosphorylatable fragment/epitope of tau which is the aspect of the invention *to which patentability is attributed.*

A "basic" and "novel" characteristic of the present invention is that the compositions and methods are useful for the production of antibodies that differentiate between tau protein that is phosphorylated at Serine 262 versus tau protein that is not. It is thus inconsequential whether "addition of another amino acid molecule to either end of a fragment would materially affect the basic and novel characteristic(s) of the claimed invention, as suggested by the Examiner. Adding additional amino acids to the basic structure as claimed does not affect patentability of the structure. Certainly modifying a peptide materially affects the essential structure of that peptide *from a biochemical standpoint*, but *from a legal standpoint*, the claimed invention is the recited structure which is essential to patentability and patentability is not affected by, for example, the presence of additional amino acids as long as the modified peptide *consists essentially of* the recited structure and generates the recited immunological response. If a peptide so-modified does not evoke the desired immune response, it falls outside the scope of the claim.

The Applicants submit that the Examiner, while scientifically correct, has misconstrued the legal meaning of the recited transitional phrase. According, the rejection may properly be withdrawn.

CONCLUSION

In view of the above arguments and amendments, Applicants believe the pending application is in condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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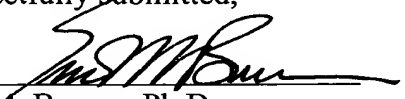
Respectfully submitted,

By 

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